



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-D-0901]

Abbreviated New Drug Application Submissions--Prior Approval Supplements Under Generic Drug User Fee Amendments; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled "ANDA Submissions--Prior Approval Supplements Under GDUFA." The Generic Drug User Fee Amendments of 2012 (GDUFA) enables FDA to assess user fees to fund critical and measurable improvements to FDA's generic drugs program. This guidance is intended to assist applicants preparing to submit to FDA prior approval supplements (PASs) and amendments to PASs for abbreviated new drug applications (ANDAs). It describes FDA's performance metric goals for PASs and clarifies how FDA will handle a PAS and amendments to a PAS for an ANDA subject to GDUFA performance metric goals. This guidance finalizes the draft guidance issued on July 11, 2014.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to

<http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-D-0901 for "ANDA Submissions--Prior Approval Supplements Under GDUFA." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions,"

publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:
<http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, rm. 3128, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Tamara R. Coley, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903, 240-402-6903 or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20903-0002, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled "ANDA Submissions--Prior Approval Supplements Under GDUFA." On July 9, 2012, the President signed GDUFA (Pub. L. 112-144, Title III) into law. GDUFA is based on an agreement negotiated by FDA and representatives of the generic drug industry to address a growing number of regulatory challenges. GDUFA aims to ensure timely access to safe, high-quality, affordable generic drugs. GDUFA enables FDA to assess user fees to fund critical and measurable

improvements to FDA's generic drugs program and to bring greater predictability and timeliness to the review of generic drug applications.

GDUFA requires that FDA and human generic drug manufacturers meet certain commitments. In the GDUFA Commitment Letter, FDA committed to review and act on a certain percentage of PASs within a specified period from the date of submission for receipts in fiscal years 2015 to 2017. The percentage of PASs that FDA has committed to review and act on increases with each fiscal year, and the deadlines for review depend on whether a PAS requires an inspection.

This guidance describes the performance metric goals to which FDA agreed in the Commitment Letter and clarifies how FDA will review a PAS and amendments to a PAS for an ANDA subject to the GDUFA performance metric goals. The GDUFA performance metrics described in this guidance only apply to ANDA applicants who electronically submit a PAS on or after October 1, 2014. These performance metrics do not apply to new drug applications (NDAs), biologics license applications (BLAs), supplements filed for NDAs or BLAs, or changes being effected supplements and annual report filings to NDAs, BLAs, or ANDAs.

This guidance finalizes the draft guidance that was issued under the same title on July 11, 2014 (79 FR 40112), and reflects FDA's consideration of public comments on the draft guidance. Generally, FDA revised the draft guidance to provide clarifying and explanatory information that will assist human generic drug manufacturers with PAS submissions. Changes from the draft guidance include clarification on the point at which a PAS is deemed submitted to FDA and a description of the process through which applicants may request FDA reconsider its supplement reporting category determination. The draft guidance and related public comments are publicly available in Docket No. FDA-2014-D-0901.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "ANDA Submissions --Prior Approval Supplements Under GDUFA." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information for supplements and amendments in 21 CFR part 314 have been approved under OMB control number 0910-0001. The collection of information for manufacturer registration in 21 CFR part 207 has been approved under OMB control number 0910-0045. The collection of information for manufacturer compliance with current good manufacturing practices in 21 CFR part 211 has been approved under OMB control number 0910-0139.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryinformation/Guidances/default.htm>, or <http://www.regulations.gov>.

Dated: October 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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